incentive in the form of allowance etc. to ensure their presence in rural areas.

Regulation of Clinical Research

2672. DR. T. SUBBARAMI REDDY:
DR. KARAN SINGH:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether international scientific journals recently raised doubts on credibility of certain drug research work in India;

(b) whether his Ministry is taking steps to regulate clinical research.

(c) if so, whether Government have set up a Central Drug Standard Control Organisation under Drug Controller General of India for the purpose:

(d) whether Government have contacted a panel of regulators mostly eminent doctors and researchers to inspect the research sites in their zones; and

(e) if so, to what extent these steps will be helpful to regulate clinical research?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) to (e) Certain country specific issues such as lack of clear regulatory norms and intellectual property right issues were earlier considered barriers to global clinical research development in India. Now, regulations for conducting clinical trials in the country have been prescribed under Rules-122DA-122E & Schedule-Y to the Drugs and Cosmetics Rules, 1945.

Good Clinical Practices (GCP), an ethical and scientific quality standard for designing and conducting and recording trials data etc. has been published in 2001. Ethical guidelines for conducting human trials have also been published by Indian Council of Medical Research (ICMR) in 2000.

In the past clinical trials in India, pertaining to totally new molecules have been very miniscule. However, this trend is now changing and the numbers of multicentric global clinical trials in India is expected to increase.

CDSCO has, therefore evolved a strategy to start inspections of clinical trial centers.

Number of workshops have already been held in coordination with Department of Pharmacology, BYL Nair Hospital, Mumbai along with centers at AIIMS, New Delhi, Pondicherry, Kolkata, Hyderabad to develop necessary Standard Operating Proceduresm (SOPs), protocols etc. A training programme for the prospective inspectors of clinical trials was conducted in New Delhi on 20-21 September 2005 with support from WHO and in partnership with various medical experts and researchers from pharma industry to develop competence and capacity to undertake inspections/ audits.

These measures will significantly enhance standards of clinical trials and will address the prevailing perception about likely exploitation of Indian study subjects, especially the poor and illiterate.

Physiotherapy Units as per WHO norms

2673. SHRI BASHISTHA NARAIN SINGH: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) what are the norms of the WHO for space requirements for providing gym and electrography and other physiotherapy units in hospitals;

(b) what is the area provided to different units of physiotherapy of Safdarjung Hospital;

(c) whether area provided for different units of Physiotherapy of Safdarjung
Hospital is in conformity with WHO norms; and

(d) if not, the reasons for which WHO norms are not followed in this hospital?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) WHO. has not developed any norms or guidelines for space requirement for providing Gym, Electrotherapy and other Physiotherapy units in hospitals.

(b) Safdarjung Hospital has separate Physiotherapy Sections attached to Department of Rehabilitation, Orthopaedic and Burns and Plastic. Physiotherapy Sections in these departments are provided approximate